

REMARKS

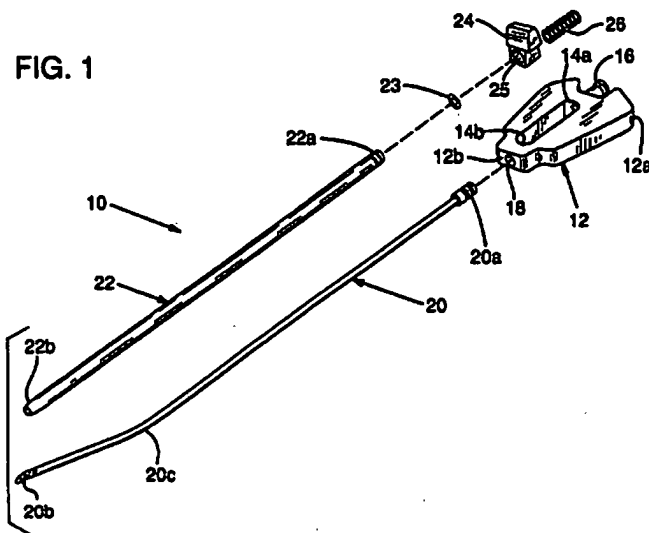
The above-identified application has been considered in view of the Office Action that was mailed on September 19, 2008. Claims 1, 4-6, 10, 11, and 21-35 are currently pending, claims 2-3, 7-9, and 12-20 having been previously canceled. By the present Amendment, Applicants have amended independent claims 1 and 28. Applicants respectfully submit that the amendments to independent claims 1 and 28 effected herein incorporate no new matter, and are fully supported by the specification. In view of these amendments, Applicants respectfully submit that claims 1, 4-6, 10, 11, and 21-35 are allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of claims 1, 4-6, 10, 11, and 21-35.

In the Office Action, claims 30 and 32-33 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,152,749 to Giesy, *et al.* (hereinafter "Giesy"). Applicants respectfully submit, however, that (i) the Office Action fails to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b), and (ii) that Giesy fails to disclose each and every element recited in claims 30 and 32-33.

Independent claim 30 recites "an instrument kit for performing a repair procedure on a meniscal tear in a knee for use in combination with a meniscal repair device." The recited instrument kit includes, *inter alia*, "a first template including a first elongate body with a first proximal end, the first elongate body defining a substantially linear configuration along an entire length thereof," "a second template including a second elongate body with a second proximal

end, the second template including a distal end portion curving in a first direction to define a first arc,” and “a third template including a third elongate body having a third proximal end, the third template including a distal end portion curving in a second direction to define a second arc, wherein the second direction is different than the first direction.”

Giesy relates to “surgical apparatus for the placement of an instrument within a body cavity.” (Col. 1, lines 5-6). In one embodiment, the disclosed apparatus constitutes a suprapubic placement device 10 that includes a needle 20 having a proximal end 20a and a bend 20c. (See col. 5, lines 38-50; see FIG. 1 reproduced below). The device 10 further includes a flexible sheath 22 including a proximal end 22a that is slidably mountable upon the needle 20. (See col. 5, lines 54-56; see FIG. 1 reproduced below).



In the Office Action, the sheath 22 was characterized as both the recited “first template” and “third template,” and the needle 20 was characterized as the recited “second template.” (See Office Action, page 2).

MPEP §2131 states that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (Citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The Examiner's argument attempts to characterize a single element of the Giesy device, i.e., the sheath 22, as two separate elements of the recited “instrument kit,” i.e., as both the recited “first template” and “third template.” Applicants respectfully submit, however, that one element of a cited reference cannot be properly said to anticipate two distinct elements of a claim. Assuming, *arguendo*, that the sheath 22 can even be accurately characterized as one of the recited “first template” or “third template,” which Applicants do not, the Giesy device is still devoid of the other. In other words, when properly interpreted, the Giesy device is devoid of either the “first template” or the “third template” recited in independent claim 30, *inter alia*. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. §102(b) fails to identify structure in the Giesy instrument that anticipates “each and every element” recited in independent claim 30, and therefore, that the rejection fails to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b).

Even if the legal insufficiency of the rejection under 35 U.S.C. §102(b) is overlooked, *arguendo*, Applicants respectfully submit that the needle 20 and the sheath 22 disclosed in Giesy fail to disclose each and every element of the “first template,” “second template,” and “third template” recited in independent claim 30.

Giesy indicates that the sheath 22, which was characterized as the recited “first template” in the Office Action, is formed of a flexible material that conforms to the shape of the needle 20 over which the sheath 22 is placed. (*See* col. 5, lines 54-55). In contrast, the “first template” recited in independent claim 30 is defined in the specification as “adapted for insertion into a knee of the patient in order to approximate a path to a meniscal tear within the knee.” (Page 6, lines 6-7). This construction facilitates insertion and manipulation “within a patient's knee to approximate a path to a meniscal tear,” as recited in independent claim 30.

Applicants respectfully submit that the flexibility of the Giesy sheath 22 renders it incapable of displacing and separating the tissue surrounding a meniscal tear within a patient's knee, and therefore, that the sheath 22 is unsuited for accomplishing the intended purpose of the templates of the present disclosure. As such, Applicants respectfully submit that the sheath 22 cannot be properly characterized as any one of the recited “first template,” “second template,” or “third template.”

For at least this reason, *inter alia*, Applicants respectfully submit that Giesy fails to disclose, or even suggest, each and every element recited in independent claim 30, and therefore, that Giesy fails to anticipate independent claim 30.

Accordingly, Applicants respectfully submit that independent claim 30 is allowable over Giesy under 35 U.S.C. §102(b). As claims 32 and 33 depend directly from independent claim 30 and include each element recited therein, for at least the reasons that independent claim 30 is allowable over Giesy under 35 U.S.C. §102(b), *inter alia*, Applicants respectfully submit that claims 32 and 33 are also allowable over Giesy under 35 U.S.C. §102(b).

Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Giesy in view of U.S. Patent No. 7,153,307 to Scribner, *et al.* (hereinafter "Scribner"). Applicants respectfully submit, however, that the combination of Giesy and Scribner fails to suggest the subject matter recited in claim 31 as a whole.

In the Office Action, the Examiner acknowledged that Giesy fails to disclose a handle and a template with an interface that can be properly labeled as a "snap-fit arrangement," as recited in claim 31, and Scribner was relied upon for disclosure of this concept.

As discussed above, Giesy fails to disclose an instrument kit including "a first template," "a second template," and "a third template," as recited in independent claim 30, or structure that can properly be characterized as a "template" at all, for that matter, suitable for insertion and manipulation "within a patient's knee to approximate a path to a meniscal tear," as further recited in independent claim 30. Assuming, *arguendo*, that the characterization of Scribner offered in the Office Action is accurate, including the snap-fit interface purportedly disclosed therein would fail to cure these deficiencies in Giesy.

For at least this reason, *inter alia*, Applicants respectfully submit that the combination of Giesy and Scribner fails to suggest each and every element recited in independent claim 30, and therefore, that independent claim 30 is allowable over Giesy in view of Scribner under 35 U.S.C. §103(a). As claim 31 depends directly from independent claim 30 and includes each element recited therein, for at least the reasons that independent claim 30 is allowable over Giesy in view of Scribner under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claim 31 is also allowable over Giesy in view of Scribner under 35 U.S.C. §103(a).

Claims 34 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Giesy. Applicants respectfully submit, however, that Giesy fails to suggest the subject matter recited in claims 34 and 35 as a whole.

In the Office Action, the Examiner acknowledged that Giesy fails to disclose the specific arc ranges recited in claims 34 and 35, but asserted that modifying the structure disclosed in Giesy as claimed would have been obvious to one of ordinary skill in the art at the time the invention was made.

As discussed above, Giesy fails to suggest the subject matter recited in independent claim 30 as a whole. Assuming, *arguendo*, that modifying the structure disclosed in Giesy as suggested by the Examiner would have been obvious to one of ordinary skill in the art at the time the invention was made, such modification would fail to cure the aforescribed deficiencies in Giesy.

For at least this reason, *inter alia*, Applicants respectfully maintain that Giesy fails to suggest each and every element recited in independent claim 30, and therefore, that independent claim 30 is allowable over Giesy under 35 U.S.C. §103(a). As claims 34 and 35 depend directly from independent claim 30 and include each element recited therein, for at least the reasons that independent claim 30 is allowable over Giesy under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 34 and 35 are also allowable over Giesy under 35 U.S.C. §103(a).

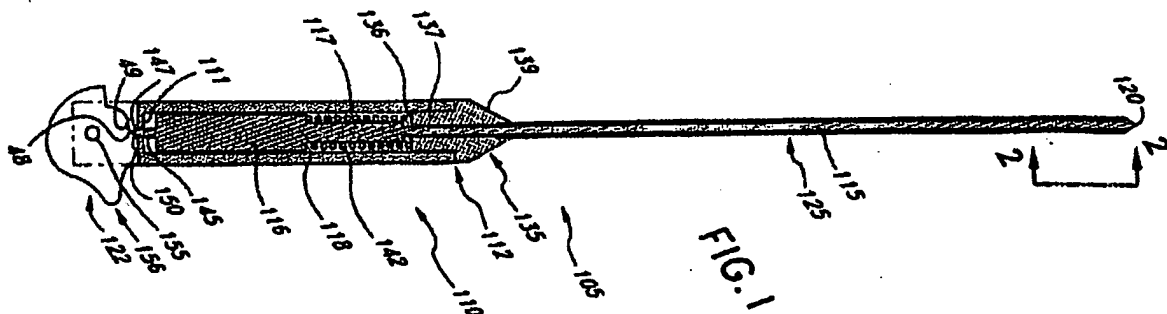
Claims 1, 4-6, 21-23, and 25-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,439,467 to Benderev *et al.* (hereinafter "Benderev") in view of U.S. Patent No. 4,635,637 to Schreiber (hereinafter "Schreiber"), U.S. Patent No. 3,842,824 to Riza (hereinafter "Riza"), and Scribner. Applicants respectfully submit, however, that the combination of Benderev, Schreiber, Riza, and Scribner fails to suggest the subject matter of claims 1, 4-6, 21-23, and 25-29 as a whole.

As amended, independent claims 1 and 28 each recite "[a]n instrument kit for performing a repair procedure on a meniscal tear in a knee for use in combination with a meniscal repair device." The recited instrument kit includes "at least one template" including, *inter alia*, "attachment structure formed at a proximal end thereof" and

a handle having receiving structure formed at a distal end thereof corresponding in configuration to the attachment structure of the at least one template, the receiving structure being configured to selectively receive the attachment structure in a snap-fit arrangement such that the at least one template is releasably

engagable with the handle, wherein the snap-fit arrangement enables the application of both a proximally directed longitudinal force and a distally directed longitudinal force to the elongate body to facilitate access to and removal from the meniscal tear by the at least one template.

Benderev discloses a method for “the treatment of stress urinary incontinence ‘SUI,’ and in particular, to improved, methods and surgical devices for the surgical treatment of SUI in females.” (Col. 1, lines 10-13). In one embodiment, Benderev describes a suture passer 105 including a handle 110, an axially movable probe 115, and a probe guide 125 having a suture channel 130. (See col. 4, lines 41-45; see FIG. 1 reproduced below).



In the Office Action, the Examiner characterized the Benderev suture passer 105 as the recited “at least one template,” and argued that the suture passer 105 “would be sufficient to access a meniscal repair.” (Office Action, page 4). The Examiner acknowledged, however, that Benderev fails to disclose various elements and features of the recited “at least one template,” e.g., “a height along the Z-axis and a width along the Y-axis, the width being substantially less than the height” and “an atraumatic tip . . . defining a dimple formed therein that is configured

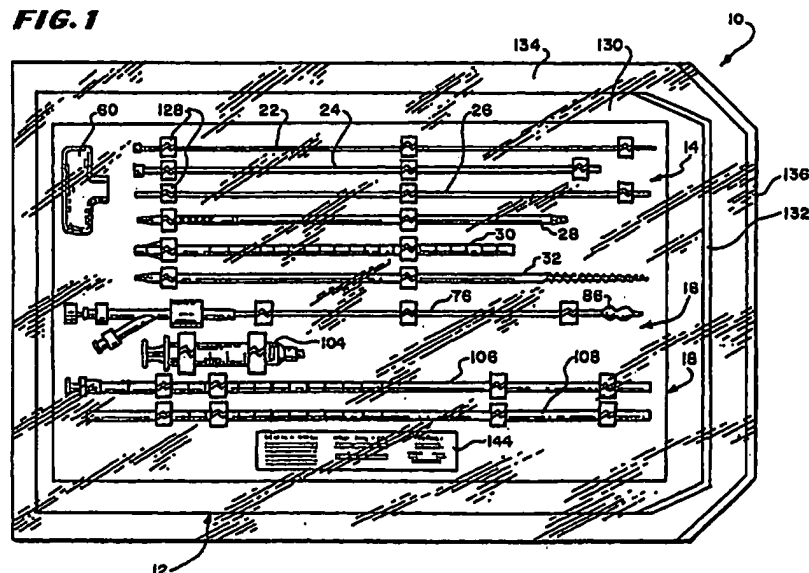
and adapted to engage a fastener,” and relied on Schreiber for disclosure of these concepts. (*See* Office Action, pages 4-5).

Regarding the combination of Benderev and Schreiber, the Examiner also acknowledged that the combination of these references fails to disclose additional features of the recited “kit,” e.g., the “attachment structure” formed at a proximal end of the at least one template and “a handle having receiving structure formed at a distal end thereof corresponding in configuration to the attachment structure of the at least one template,” and relied upon Riza for disclosure of such structure. (*See* Office Action, pages 5-6). With respect to the combination of Benderev, Schreiber, and Riza, the Examiner further acknowledged that the combination of these references fails to disclose the recited “snap-fit arrangement” between the “attachment structure” and the “receiving structure,” and relied upon Scribner for disclosure of this concept. (*See* Office Action, page 6).

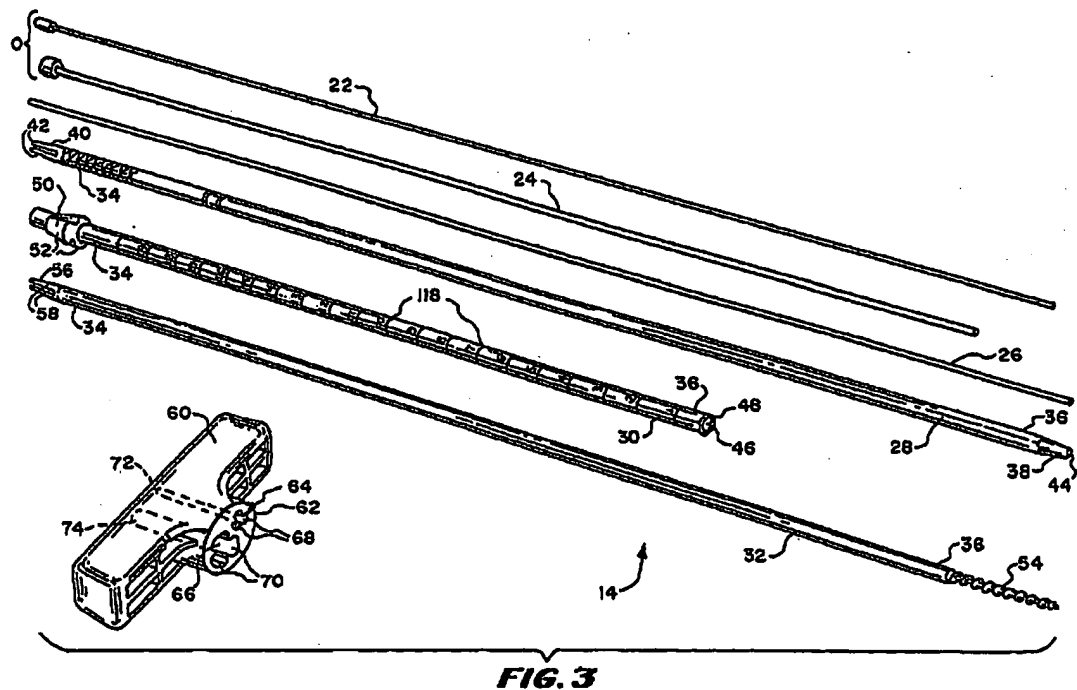
Assuming, *arguendo*, that the characterizations of Benderev, Schreiber, and Riza offered in the Office Action are accurate, Applicants respectfully submit that Scribner fails to disclose the unique combination of elements and features recited in independent claims 21 and 28 as presented herein.

In accordance with the discussion below, Applicants respectfully submit that Scribner fails to disclose the “snap-fit arrangement” between “attachment structure” formed at a proximal end of a template and “receiving structure” formed at a distal end of a handle, as recited in the version of independent claims 21 and 28 presented previously. However, in the interests of

Scribner relates to “the treatment of bone conditions.” In one embodiment, Scribner discloses a system 10 of instruments including instruments 28, 30, and 32, (*see* col. 5, line 58; *see* col. 6, line 30; *see* FIG. 1 reproduced below), and a handle 60 that for engagement therewith. (*See* col. 7, lines 40-41; *see* FIG. 1 reproduced below).



In the Office Action, the Examiner argued that the handle 60 of the Scribner system 10 is connectable with the instruments 28, 30, 32 in snap-fit arrangement, referring to FIG. 3 of Scribner, which has been reproduced below. However, Applicants respectfully disagree with the Examiner's characterization of the connection between the handle 60 and the instruments 28, 30, 32.



Scribner specifically indicates that the handle 60 engages the instruments 28, 30, 32 in "slip fit fashion," (col. 7, line 42), and not in the recited "snap-fit arrangement." More particularly, Scribner disclose that the handle 60 includes two interior sockets 64, 66 with an array of circumferentially spaced grooves 68 that match teeth 42, 58 formed at the proximal ends

34 of the instruments 28, 32, respectively. (See col. 7, lines 55-64; see FIG. 3 reproduced above). According to Scribner, the slip fit engagement between the sockets 64, 66 and the teeth 42, 58 “*prevents relative rotation* between either instrument 28 or 32 and the first socket 64, thereby permitting torsional or twisting forces to be applied to either instrument 28 or 32 by the handle 60.” (emphasis added) (Col. 8, lines 4-7). Additionally, U.S. Patent No. 6,468,279 indicates that the slip fit permits quick detachment of the instrument from the handle without sticking or resort to inordinate force. (See col. 7, lines 46-49).

While the slip fit engagement between the Scribner handle 60 and the instruments 28, 32 may facilitate distal advancement of the instruments 28, 32, the slip fit engagement is configured, dimensioned, and intended to prevent relative rotation between the handle 60 and the instruments 28, 32, and is incapable of applying a proximally directed force to the instruments 28, 32. In fact, as highlighted above, the ‘279 patent specifically discloses that the slip-fit engagement substantially eliminates any sticking such that the handle and the instruments can be separated without any “inordinate force.” (See col. 7, lines 46-49). Thus, Applicants respectfully submit that the Scribner handle is specifically designed to separate from the instruments 28, 32 upon the application of a proximally directed force to the handle 60, and that any force communicated to the instruments 28, 32 via the handle 60 would be insufficient to facilitate movement of the instruments 28, 32 in the proximal direction, particularly when movement of the instruments 28, 32 is restricted through engagement with a patient’s tissue.

Accordingly, Applicants respectfully submit that Scribner fails to disclose, or even suggest, “receiving structure being configured to selectively receive the attachment structure in a snap-fit arrangement such that the at least one template is releasably engagable with the handle,” “wherein the snap-fit arrangement enables the application of both a proximally directed longitudinal force and a distally directed longitudinal force to the elongate body to facilitate access to the meniscal tear by the at least one template.”

For at least this reason, *inter alia*, Applicants respectfully submit that Scribner fails to cure the deficiencies in the combination of Benderev, Schreiber, and Riza acknowledged by the Examiner in the Office Action and discussed above, and therefore, that the combination of Benderev, Schreiber, Riza, and Scribner fails to suggest the subject matter recited in amended independent claims 1 and 28 as a whole. As such, Applicants respectfully submit that independent claims 1 and 28 are allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a). As claims 4-6, 21-23, 25-27, and 29 depend either directly or indirectly from amended independent claims 1 and 28 and include each element recited therein, for at least the reasons that amended independent claims 1 and 28 are allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 4-6, 21-23, 25-27, and 29 are also allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a).

Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Benderev in view of Schreiber, Riza, and Scribner. Applicants respectfully submit, however, that the

combination of Benderev, Schreiber, Riza, and Scribner fails to suggest the subject matter recited in claim 24 as a whole.

In the Office Action, the Examiner acknowledged that that the combination of Benderev, Schreiber, Riza, and Scribner fails to disclose a bore that is “substantially rectangular in shape and orthogonally oriented with respect to the groove,” as recited in claim 24, but asserted that such elements and features would have been an obvious matter of design choice to one of ordinary skill in the art.

As set forth above, the combination of Benderev, Schreiber, Riza, and Scribner fails to suggest the subject matter of amended independent claim 1 as a whole. Assuming, *arguendo*, that including a “substantially rectangular in shape and orthogonally oriented with respect to the groove” would have been obvious to one of ordinary skill in the art, the inclusion of such structure and features would fail to cure the deficiencies in the combination of Benderev, Schreiber, Riza, and Scribner discussed above.

Accordingly, and for at least this reason, *inter alia*, Applicants respectfully maintain that amended independent claim 1 is allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a). As claim 24 depends indirectly from amended independent claim 1 and includes each element recited therein, for at least the reasons that amended independent claim 1 is allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claim 24 is also allowable over Benderev in view of Schreiber, Riza, and Scribner under 35 U.S.C. §103(a).

Claims 10-11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Benderev in view of Schreiber, Riza, and Scribner as applied to claim 1, and further in view of U.S. Patent Application Publication No. 2002/0002374 to Barreiro, *et al.* (hereinafter "Barreiro"). Applicants respectfully submit, however, that the combination of Benderev, Schreiber, Riza, Scribner, and Barreiro fails to suggest the subject matter recited in claims 10-11 as a whole.

In the Office Action, the Examiner acknowledged that that the combination of Benderev, Schreiber, Riza, and Scribner fails to disclose the recited "disposable loading units," and Barreiro was relied upon for disclosure of this concept.

As set forth above, the combination of Benderev, Schreiber, Riza, and Scribner fails to suggest the subject matter of amended independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's proffered characterization of Barreiro is accurate, including the "disposable loading units" purportedly disclosed therein would fail to remedy the aforescribed deficiencies in the combination of Benderev, Schreiber, Riza, and Scribner.

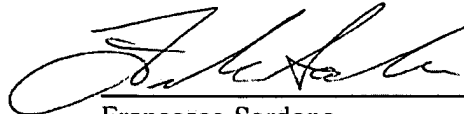
For at least this reason, *inter alia*, Applicants respectfully submit that the combination of Benderev, Schreiber, Riza, Scribner, and Barreiro fails to suggest the subject matter recited in amended independent claim 1 as a whole, and therefore, that amended independent claim 1 is allowable over Benderev in view of Schreiber, Riza, Scribner, and Barreiro under 35 U.S.C. §103(a). As claims 10 and 11 depend directly and indirectly from amended independent claim 1, respectively, and include each element recited therein, for at least the reasons that amended

independent claim 1 is allowable over Benderev in view of Schreiber, Riza, Scribner, and Barreiro under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 10 and 11 are also allowable over Benderev in view of Schreiber, Riza, Scribner, and Barreiro under 35 U.S.C. §103(a).

In view of the amendments to the claims effected herein, and the foregoing remarks and arguments, Applicants respectfully submit that the subject matter recited in claims 1, 4-6, 11, and 21-35 is patentably distinguishable from that disclosed in cited references of record. Accordingly, Applicants respectfully request reconsideration and allowance of these claims.

Should the Examiner feel that an interview may facilitate the resolution of any remaining matters, the Examiner is sincerely invited to contact Applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,



Francesco Sardone
Reg. No.: 47,918
Attorney for Applicants

CARTER, DELUCA, FARRELL, & SCHMIDT, LLP
445 Broad Hollow Road, Suite 420
Melville, New York 11747
Phone: (631) 501-5700
Fax: (631) 501-3526
FS/nr